EXHIBIT 507

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

MDL NO: 1968

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION,
_____/

100 N. Tampa Street
Suite 2900
Tampa, FL 33602
January 25, 2011
at 9:08 a.m.

VIDEOTAPE DEPOSITION OF DAVID BLIESNER, Ph.D.

Taken on behalf of the Defendants before PHILIP RYAN, RPR, Court Reporter, Notary Public in and for the State of Florida at Large, pursuant to Defendant's Notice of Taking Deposition in the above cause.

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ALSO PRESENT:
Alan Pokotilow, videographer

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THE VIDEOGRAPHER: My name is Alan Pokotilow with Veritext. The date today is January 25 of 2011. The time is approximately 9:08 a.m. 09:08

This deposition is being held at the office of Shook, Hardy & Bacon, located at 100 North Tampa in Tampa, Florida. 09:08

The caption of the case is in regards to Digitek product liability litigation, MDL number 168, to be heard in United States District Court of the Southern District of West Virginia, Charleston Division. 09:08

The name of the witness is Dr. David Bliesner. 09:08

At this time the attorneys will please identify themselves and the parties they represent, after which then our court reporter Phil Ryan of Veritext will swear the witness and we can proceed. 09:08

MR. MORIARTY: My name is Matt Moriarty, and I represent the Actavis Defendants. 09:09

MR. ANDERTON: Michael Anderton also on behalf of the Actavis defendants. 09:09

MS. DONAHUE: Alicia Donahue, Shook 09:09

Hardy & Bacon on behalf of the Mylan Defendants and UDL Laboratories. 09:09

MR. KERENSKY: And for the Plaintiffs we have Mike Kerensky, Terry Fitzpatrick, and Meghan Johnson Carter. 09:09

THE VIDEOGRAPHER: Would the court reporter please swear the witness. 09:09

The Deponent herein, 09:09

DAVID BLIESNER, Ph.D., 09:09

being first duly sworn to tell the truth, the whole truth, and nothing but the truth, was examined and testified as follows: 09:09

DIRECT EXAMINATION 09:09

BY MR. MORIARTY: 09:09

Q. Tell us your name. 09:09

A. David Bliesner. 09:09

Q. Okay. Have you ever given testimony in court before? 09:09

A. When you say "testimony"? 09:09

Q. Gone into court, been sworn and testified. 09:09

A. In court? 09:09

Q. In court. 09:09

A. No. 09:09

Q. How about in an arbitration 09:09

proceeding? 09:09
A. Yes. 09:09
Q. What kind of arbitration proceeding was that? 09:10
A. It was an HR arbitration. 09:10
Q. Does that stand for human resources? 09:10
A. Yes. 09:10
Q. All right. So this was some sort of employment dispute at one of your jobs or your consulting arrangements? 09:10
A. It wasn't employment dispute, no. 09:10
Q. All right. Were you just a witness or had you been sued in the case or were you suing somebody else? 09:10
A. I was a witness. 09:10
Q. Have you only testified in one arbitration proceeding? 09:10
A. Just one arbitration, yes. 09:10
Q. Have you ever given a deposition such as we're about to do today? 09:10
A. Yes. 09:10
Q. How many times have you done that? 09:10
A. One time. 09:10
Q. What sort of case was it? 09:10
A. Probate. 09:10

Q. All right. So you have never testified in a pharmaceutical products liability case in deposition? 09:11

A. No. 09:11

Q. How many times have you been retained as an expert witness in a pharmaceutical products liability case? 09:11

A. One time. 09:11

Q. Just this time? 09:11

A. Yes. 09:11

Q. All right. Now, do you know who Pete Miller is? 09:11

A. Yes. 09:11

Q. He's one of the Plaintiffs' lawyers in this Digitek litigation; correct? 09:11

A. Yes. 09:11

Q. When was the last time you met Pete Miller in person? 09:11

A. Yesterday. 09:11

Q. Where was that? 09:11

A. At the Sheraton. 09:11

Q. And how long did you spend with Pete Miller? 09:11

A. Several hours. 09:11

Q. Mr. Kerensky was just here a second 09:12

ago. When did you first meet him in person? 09:12
A. Yesterday. 09:12
Q. How long did you spend with him? 09:12
A. A couple of hours. 09:12
Q. All right. When did you first meet 09:12
Mr. Fitzpatrick? 09:12
A. Yesterday. 09:12
Q. How long did you spend with him? 09:12
A. Several hours. 09:12
Q. And you've met Meghan before; correct? 09:12
A. Correct. 09:12
Q. Are there any other lawyers for the 09:12
Plaintiffs in the Digitek litigation with whom you 09:12
have met either in person or by telephone? 09:12
A. I'm not good with legal terms. So 09:12
Plaintiff, please? 09:12
Q. The people who are suing the 09:12
pharmaceutical companies. 09:12
A. Could you ask the question again, 09:12
please? 09:12
Q. Sure. Other than the people I've just 09:12
named, have you met with -- either in person or by 09:12
phone -- any other Plaintiffs' lawyers in the 09:12
Digitek litigation? 09:12
A. By phone, yes. 09:12

Q. Who? 09:12
A. I don't recall who was on the 09:12
teleconference. 09:13
Q. How many people were on the 09:13
teleconference? 09:13
A. I don't know the exact number. 09:13
Q. And when was that telephone conference? 09:13
A. I believe it was in January of last 09:13
year. 09:13
Q. Now, I'll get in -- later into more 09:13
detail about what you did to prepare for today, 09:13
but do you know who Russ Soma is? 09:13
A. No. 09:13
Q. How about Mr. Kenny? 09:13
A. No. 09:13
Q. Jim Farley? 09:13
A. No. 09:13
Q. Karen Frank? 09:13
A. No. 09:13
Q. Each one of those people were hired by 09:13
the Plaintiffs' lawyers and wrote reports much 09:13
like you wrote here with your opinions about this 09:13
Digitek situation. 09:14
Have you ever read any of those reports? 09:14
A. Not to my knowledge, no. 09:14

Q. Did any of the Plaintiffs' lawyers read to you from those reports? 09:14
A. No. 09:14
Q. Recently in December of 2010 we produced to the other side reports of our experts -- Lou Amsel, Martha Bennett, several other people. 09:14
Have you seen any of those reports? 09:14
A. Not that I recall. 09:14
Q. To the best of your knowledge, have any of the Plaintiffs' lawyers read to you from those reports? 09:14
A. Not that I recall. 09:14
Q. Have they told you in general what those reports contain and what their conclusions were? 09:15
A. No. 09:15
Q. Last June and then even last week I took and Mr. Anderton took and a Mr. Dean from my office took testimony from Russ Soma, Mr. Kenny, Karen Frank and Jim Farley; okay? 09:15
Have you seen any of those deposition transcripts? 09:15
A. Who are those individuals again? 09:15
Q. They are experts hired by the same people who hired you. 09:15
A. I don't recognize those names. 09:15

Q. But have you read any of their deposition testimony? 09:15 09:16

A. Not that I recall. 09:16

Q. Did the Plaintiffs' lawyers read to you any excerpts from their transcripts? 09:16 09:16

A. No. 09:16

Q. When you met with these lawyers yesterday to get ready for today, did they tell you any of the kind of questions that you could expect from me? 09:16 09:16 09:16 09:16

A. Yes. 09:16

Q. All right. I assume that since you have both a college degree from a very reputable institution and a Ph.D., that you have had to study for and take examinations in your career; is that correct? 09:16 09:16 09:16 09:16 09:16

A. Yes. 09:16

Q. Did you ever have an occasion in your academic career when you studied real hard for a test but did poorly? 09:16 09:16 09:16

A. Specifically I don't recall. 09:17

Q. Did you ever have an occasion where you didn't study too hard at all but you did rather well? 09:17 09:17 09:17

A. Specifically I don't recall. 09:17

Q. All right. Generally do you recall? 09:17
A. Vaguely. 09:17
Q. And is it your vague recollection that those two things probably happened at some point in your academic career? 09:17
A. Perhaps. 09:17
Q. All right. So if perhaps that happened, you would agree with me logically that the amount of work put in the process of studying did not always necessarily correlate with the outcome; right? 09:17
A. Could you say that again, please. 09:18
MR. MORIARTY: Can you read that back? 09:18
(Whereupon, the testimony was read back by the court reporter, as recorded above) 09:18
THE WITNESS: I wouldn't agree with you on that statement. 09:18
BY MR. MORIARTY: 09:18
Q. All right. Are you a golf fan? 09:18
A. No. 09:18
Q. Do you still shoot and skeet or trap tournaments competitively? 09:18
A. No. 09:18
Q. Did you ever do that? 09:18
A. No. 09:18

Q. Do you still coach? 09:18
A. I don't know if I understand what you 09:19
mean by "coach." 09:19
Q. Well, you have a website that talks 09:19
about your online shotgun classes. I think it 09:19
even says the word "coach." 09:19
Do you still do that? 09:19
A. I don't know if I understand what you 09:19
mean by "coach." 09:19
Q. Did you ever play any sports in high 09:19
school or -- 09:19
A. Yes. 09:19
Q. -- college? 09:19
A. Yes. 09:19
Q. Did you have coaches? 09:19
A. Yes. 09:19
Q. Elders, those with more experience who 09:19
taught you how to block or tackle or do freestyle 09:19
better? 09:19
A. Whatever sport. 09:19
Q. Okay. So you do have a website that 09:19
talks about you being the online coach? 09:19
A. No, it does not talk about me being the 09:19
online coach. 09:19
Q. Okay. I want to make sure I'm not 09:19

misquoting anything. Is the name of the website still claycoachonline.com? 09:20

A. It is. 09:20

Q. So the word "coach" is in the title of the website; correct? 09:20

A. It is, correct. 09:20

Q. All right. 09:20

So what is it? 09:20

A. It's what it says on the web page there. 09:20

Q. Yeah, but what is it? Is it just a video system that you sell? 09:20

A. It's more than a video system. 09:21

Q. But you don't do one-on-one coaching with people; right? 09:21

A. Again, how do you define "coaching"? 09:21

Q. Teaching, encouraging, helping them improve, trying to tell them about their technique. 09:21

A. Professionally, for a fee? 09:21

Q. I didn't ask that. Do you do that at all, whether for free or for a fee? 09:21

A. Coaching again, you know, I have children. I coach all the time. 09:21

Q. Okay. Do you know the difference between probability and possibility? 09:21

A. From a legal term? 09:21
Q. Do you know the difference between 09:21
probability and possibility? 09:22
A. In what context? 09:22
Q. Any context. 09:22
A. No. 09:22
Q. So in your work as -- in the 09:22
pharmaceutical business and then as a 09:22
pharmaceutical consultant, you've never understood 09:22
the distinction between possibility and 09:22
probability? 09:22
A. I don't recall whether I've ever sat 09:23
down and thought about the difference between the 09:23
two. 09:23
Q. Okay. Do -- does adherence with GMPs 09:23
absolutely guarantee that a drug product will be 09:23
within its specifications all the time? 09:23
A. Could you say that again, please. 09:23
MR. MORIARTY: Would you read that back, 09:23
please? 09:23
(Whereupon, the testimony was read 09:23
back by the court reporter, as recorded above) 09:23
THE WITNESS: When you say GMPs, what 09:23
specifically are you talking about? 09:24
BY MR. MORIARTY: 09:24

Q. Do you go by Dr. or Mr.? 09:24
A. Doctor. 09:24
Q. Okay. Dr. Bliesner, it has been represented to me in your resume, in your website, and in this lengthy report that you authored in the Digitek case, that you are an expert in GMPs for the pharmaceutical industry. 09:24
A. That is true. 09:24
Q. So why are you asking me what I mean by GMPs? 09:24
A. I'm not sure if you understand the definition of GMPs in some context. Some people don't. 09:24
Q. Well, I do. 09:24
A. Okay. 09:24
Q. Okay. So can you answer my question? 09:24
A. Are we talking about 21 CFR 210 and 211? 09:24
Q. You got other GMPs for the pharmaceutical industry? 09:24
A. There's currently industry practices that sometimes people -- 09:24
Q. No, GMPs. 09:24
A. 21 CFR 210, 211? 09:24
Q. Yes, sir. 09:24

A. Okay. And your question again, please. 09:24
Q. Does adherence with GMPs guarantee to 09:24
100 percent certainty that a drug product will 09:25
always meet its specifications as set forth in the 09:25
United States pharmacopeia? 09:25
A. Following the GMPs; right? I just want 09:25
to make sure I understand what your question is. 09:25
That you're saying if you follow the GMPs, then 09:25
there's a 100 percent guarantee that those 09:25
products will be -- what was the term? 09:25
Q. Within their specs. 09:25
A. Within their specs. There's no 09:25
guarantee, 100 percent guarantee. 09:25
Q. Okay. So you would agree with me that 09:25
adherence with GMPs increases the chances that 09:25
they will be within the specs; is that right? 09:25
A. Could you say that again, please? 09:26
MR. MORIARTY: Can you read it back, 09:26
please. 09:26
(Whereupon, the testimony was read 09:26
back by the court reporter, as recorded above) 09:26
THE WITNESS: The GMPs are a minimum 09:26
standard that's laid out by the federal 09:26
government. 09:26
BY MORIARTY: 09:26

Q. That wasn't my question. My question is whether in your opinion adherence to the GMPs increases the chances that a drug product will meet its USP specs. 09:26

A. Possibly. 09:26

Q. Now you used the word "possibly." 09:26

A. Uh-huh. 09:26

Q. You told me earlier you don't know the difference between possibility and probability. So tell me what you mean by possibility or possibly in that answer. 09:26

A. Previously I actually said I've never sat down and thought about the difference between possibility and possibility. In this case you're asking me what I mean by possibly. 09:27

Q. Yeah, what do you mean by possibly in that answer? 09:27

A. Again, the GMPs are a minimum set of standards. They're designed to provide operating space if you will, to produce drugs that are safe and effective. And just because you follow them doesn't guarantee that everything you make falls into those categories. 09:27

Q. Okay. But if you adhere to them, does it increase the chances that you will meet the 09:27

ANDA or NDA or USP specs for that drug? 09:27

A. I don't think that you can say just 09:28

because you follow the law it makes your product 09:28

going to be better. 09:28

Q. Okay. Have you ever heard of the 09:28

scientific method? 09:28

A. Yes. 09:28

Q. What is it? 09:28

A. Scientific method is a systematic means 09:28

of developing a hypothesis, collecting data. 09:28

After doing experiments, analyzing the data, 09:28

drawing conclusions to try to support or detract 09:28

from your hypothesis. 09:28

Q. Is the scientific method best achieved 09:28

when you actually look at the underlying data as 09:28

opposed to somebody's interpretation of the data? 09:29

A. The scientific method is an approach to 09:29

collecting data. 09:29

Q. Okay. But in order to reach 09:29

scientifically valid conclusions, should you look 09:29

at the actual data as opposed to somebody's 09:29

interpretation of the data? 09:29

A. I don't know if I understand exactly 09:29

your question. 09:29

Q. Well, in your -- in your reading to 09:29

prepare opinions in this case, you read this article by Jerry Bauman and Robert Didomenico and William Galanter about Digoxin; correct? 09:29 09:29 09:30

A. May I see it? 09:30

Q. Sure. That Post-It may even say what the reference was in your report. 09:30 09:30

A. May I take a moment and confirm that that is the article that I read? 09:30 09:30

Q. If you don't trust me, go ahead. 09:30

A. Okay. I need to step over here and grab a -- 09:30 09:30

Q. Go ahead. Be careful with your microphone cord. 09:30 09:30

MR. KERENSKY: Yeah, take it off. 09:30

THE WITNESS: I did review that document. 09:32 09:32

BY MR. MORIARTY: 09:32

Q. The document is an article from the medical literature, is it not? 09:32 09:32

A. Yes. 09:32

Q. Do you commonly read medical literature? 09:32

A. How do you define commonly? 09:32

Q. Well, how many articles have you read about Digoxin in the past two years? 09:32 09:32

A. I don't recall. 09:32

Q. Do you subscribe to any medical journals? 09:32

A. When you say subscribe, permanent subscription? 09:32

Q. Well, I don't expect that any subscription is permanent, but people subscribe to magazines for several years, maybe a year, maybe two, maybe for their entire career. 09:33

Do you subscribe to any medical journals? 09:33

A. I buy access to online medical journals, sites, and articles. 09:33

Q. And what sites are those? 09:33

A. I'd have to go back and look it up. 09:33

Q. But the bottom line is that this article doesn't just contain data. It contains analysis of data and editorial information about the data; correct? 09:33

A. What do you mean by editorial? 09:33

Q. Well, did you -- when did you last read that article? 09:33

A. Bless you. I don't recall. I guess probably early on when Miller firm contacted me somewhere in January. 09:34

Q. Do you read the newspaper? 09:34

A. Occasionally. 09:34

Q. Does it have an editorial section? 09:34
A. Yes. 09:34
Q. Do you know the editorial section from the rest of the newspaper? 09:34
A. Yes. 09:34
Q. So you have some idea what editorial means, don't you? 09:34
A. Yes. 09:34
Q. I'm handing you what has been marked as Exhibit 78A. 09:34
Have you ever seen that before? 09:35
A. Do you mind if I check my notes? 09:35
Q. Oh, by all means. Let me ask you this first: Do you have -- in this report that you drafted, do you repeatedly refer to 21 United States Code, Section 351, the section that defines adulteration? 09:35
A. Repeatedly. 09:36
Q. Yeah. 09:36
A. Can I see the report? 09:36
Q. Do you ever refer to it? I'm not going to quibble about the quantification. Do you ever refer to this report? 09:36
A. What's the number of that document? 09:36
Q. 21 United States Code, Section 351. 09:36

A. May I see the report, please? 09:36
Q. You have your own copy? 09:36
A. I do. 09:36
Q. See if you ever refer to the section 09:36
that defines what adulterated drug product is -- 09:36
A. Say again the code that you are 09:36
specifically citing. 09:36
Q. 351 -- 09:36
A. 21 CFR, 351? 09:36
Q. Yeah. While you're looking, tell me how 09:36
long again you took to prepare for today's 09:36
deposition -- 09:36
MR. KERENSKY: Oh, my. Let's not get 09:36
testy. It's his first deposition. He's 09:36
taking his time. Let's not get testy. 09:36
MR. MORIARTY: Okay. I'll withdraw that 09:36
question. See if you ever refer to this code 09:36
provision in your report. 09:36
THE WITNESS: On page 9, difficulty in 09:37
manufacture of Digoxin tablets have been known 09:37
for some time and the concern to FDA -- 09:37
THE COURT REPORTER: Sir, slow down. 09:37
THE WITNESS: Oh, I'm sorry. 09:37
BY MR. MORIARTY: 09:37
Q. You don't have to read all that. Just 09:37

tell me do you refer to it in the report, yes or no? 09:37

A. 21 CFR, Part 310.500? 09:37

Q. 351 United States Code. Not the code of Federal regulations, the United States code, 21 USC 351. It defines adulteration. Do you refer to that in your report? What page are you on? 09:37

A. Fifteen. 09:39

Q. Let's -- let me withdraw the question and ask you another question. 09:39

A. Okay. 09:39

Q. Do you use the word "adulterated" in your report? Without looking, do you remember off the top of your head whether you used the word "adulterated" in your report? 09:39

A. Okay. 09:40

Q. Do you know what it means? 09:40

A. Yes. 09:40

Q. Okay. Let's look back at 78A, which is the statutory definition of adulteration; okay? Have you ever seen this before? 09:40

A. This document, 78A? 09:40

Q. Have you ever seen 21 USC Section 351, the definition of adulteration? 09:40

A. I have reviewed the Federal Food, Drug 09:41

and Cosmetic Act. 09:41
Q. Okay. 09:41
A. Online. 09:41
Q. So -- 09:41
A. But I do not commit the numbers to memory. 09:41
Q. Okay. But you have seen this statute before, whether you saw it on a piece of paper or online; correct? 09:41
A. I'm not sure whether the document you have in front of me is what I reviewed online. 09:41
Q. What does that mean? Do you think you looked at a different version of the United States code or a different provision of the code? 09:41
A. Possibly. Whatever version this was that's on the website for the Government printing office. 09:42
Q. Okay. Well, do you have a copy of this in your own material that you printed and relied on for purposes of your opinions in this case? 09:42
A. 78A? 09:42
Q. Mr. Bliesner, 21 United States Code, section 351, whether it's marked as an exhibit or not. 09:42
A. Let me check. 09:42

MR. MORIARTY: Go off the record, please. 09:42

THE VIDEOGRAPHER: The time is now 9:43 a.m. and we're going off the record briefly. 09:42

(Short break) 09:57

THE VIDEOGRAPHER: The time is 9:58 a.m. We're back on the record. 09:57

BY MR. MORIARTY: 09:57

Q. In the time that you did spend looking in materials, you didn't find either 21 USC section 351 or 21, Code of Federal Regulations, Section 351, did you? 09:58

A. In my stuff? 09:58

Q. Correct. 09:58

A. No, I did not. 09:58

Q. But because the word adulteration is in your written report, presumably you know what that means; correct? 09:58

A. Yes. 09:58

Q. So what I've placed before you is Exhibit 78A. It is the United States Code definition of adulteration. 09:58

A. Okay. 09:58

Q. And I'm going to refer to Section A2(b) 09:58

1	okay. And A2(b) is -- see A right here?	09:58
2	A. Yes.	09:58
3	Q. And then there's one?	09:58
4	A. Yes.	09:58
5	Q. And then there's two and then there's	09:58
6	2(b) down here; okay?	09:58
7	A. 2(b).	09:58
8	Q. 2(b). I would like you to read A2(b) to	09:58
9	yourself.	09:59
10	MR. KERENSKY: I can't even find A2(b).	09:59
11	MR. MORIARTY: The first page, Mike.	09:59
12	THE WITNESS: Just to be clear, please.	09:59
13	It's the one that starts off, "if it is."	09:59
14	BY MR. MORIARTY:	09:59
15	Q. If it is a drug --	09:59
16	A. Yes.	09:59
17	Q. -- and the methods used in.	09:59
18	A. Okay.	09:59
19	Q. You see that?	09:59
20	A. Yes.	09:59
21	Q. Read that to yourself, please.	09:59
22	Have you read it?	09:59
23	A. Yes.	09:59
24	Q. Is that the definition of adulterated	09:59
25	with which you are familiar under circumstances	10:00

when GMPs are not complied with? 10:00
A. Yes. 10:00
Q. All right. Now, does that section A2(b) 10:00
say anything about drugs actually being outside 10:00
their specifications? 10:00
A. The word specification is not here. 10:00
Q. Does it say anything about drugs being 10:00
dangerous to consumers? 10:00
A. It applies safety. 10:00
Q. Where does the word -- 10:01
A. "As to safety and has the identity and 10:01
strength." 10:01
Q. I'm asking whether it says anything 10:01
about danger to consumers. 10:01
A. It does not say anything in that 10:01
sentence. 10:01
Q. Does it use the word -- does A2(b) use 10:01
the word defective? 10:01
A. The word defective is not here. 10:01
Q. Does A2(b) say anything about whether 10:01
these adulterated products are possibly or likely 10:01
defective or out of specification? Does that 10:01
phrase or wording appear anywhere in the statute? 10:02
A. Could you say that again, please. 10:02
MR. MORIARTY: Can you read that back? 10:02

(Whereupon, the testimony was read back by the court reporter, as recorded above) 10:02

THE WITNESS: Not right here in this sentence, no. 10:02

BY MR. MORIARTY: 10:02

Q. To the best of your knowledge, does that phrase or wording appear in the Code of Federal Regulations that mirrors this statutory definition? 10:02

A. I couldn't say because this regulation is not one that we refer to in the industry. We stay with the GMPs. This is the higher-level document and the lawyers are concerned with this. We are not, at the operational level. 10:03

Q. And when you say the GMPs, are you talking about Code of Federal Regulations, Title 21, Section 210? 10:03

A. 210 and 211. 10:03

Q. Okay. So I'm handing you what's Exhibit 75. 10:03

A. Yes. 10:04

Q. You've seen that before; correct? 10:04

A. I have. 10:04

Q. All right. So -- 10:04

A. Not this particular exhibit, but I have 10:04

seen 21 CFR 210 and 211. 10:04

Q. So when we look at 210.1(b), it says, 10:04

"The failure to comply with any regulations 10:04

set forth in this part and in parts 211 through 10:04

226 of this chapter, in the manufacture, 10:04

processing, packing and folding of a drug, shall 10:04

render such drug to be adulterated under section 10:04

501 A(2)(b) of the Act, and such drug as well as 10:04

the person who is responsible for the failure to 10:05

comply shall be subject to regulatory action." 10:05

Did I read that correctly? 10:05

A. Yes, sir. 10:05

Q. Now, is it -- is it your understanding 10:05

that this lawsuit is not a regulatory action? 10:05

A. Regulatory action on the part of the 10:05

Government, is that -- is that what you're talking 10:05

about? 10:05

Q. No, I'm asking is this lawsuit -- is it 10:05

your understanding that this lawsuit is or is not 10:05

a regulatory action? 10:05

A. It is not a regulatory action by the 10:05

Federal Government as I understand it. 10:05

Q. Okay. And that's what you understand 10:05

Exhibit 75, section 210.1(b) to mean, is a 10:05

regulatory action by the Federal Government; 10:06

correct? 10:06
A. That's how I interpret it, yes. 10:06
Q. Now, does anything in 210.1(b) refer to 10:06
out of specification, dangerous, or defective -- 10:06
by the way, please don't write on the exhibits. 10:06
A. Sorry. 10:06
Q. You really don't need your pen. 10:06
MR. KERENSKY: No, he can use his pen to 10:06
help him find it, but he will not write on it. 10:06
MR. MORIARTY: Put the cap on. 10:06
THE WITNESS: I won't write on your 10:06
documents. Sorry. 10:06
MR. MORIARTY: They're not mine anymore. 10:06
Once I give them to you, they're not mine. 10:06
THE WITNESS: I'm sorry. 10:06
BY MR. MORIARTY: 10:06
Q. The question is does 210.1(b) say 10:06
anything about out of specification, dangerous, or 10:06
defective? 10:06
A. It does not say out of specification, 10:07
dangerous, or defective in here. 10:07
Q. Does Section A say those words? 10:07
A. It's dangerous specifications and -- 10:07
Q. Dangerous, out of specification, or 10:07
defective. 10:07

A. No. 10:07
Q. All right. May have that Exhibit 75? 10:07
A. Sure. Can I have yours? 10:07
MR. KERENSKY: Sure. 10:07
BY MR. MORIARTY: 10:07
Q. Did you -- you wrote on that one, too. 10:07
Terry, can I have your 78(a)? 10:07
A. Sorry. 10:07
Q. All right. So at some point last 10:07
winter, last spring, the Plaintiffs' lawyers sent 10:08
you material to review; correct? 10:08
A. Yes. 10:08
Q. Did you review it carefully? 10:08
A. Yes. 10:08
Q. Did you talk to them before you wrote 10:08
this report? 10:08
A. In relation to the documents I was 10:08
getting, those types of things, yes. 10:08
Q. Yeah. And by the way, when we talk 10:08
about your report, we're talking about Exhibit 92, 10:08
are we not? 10:08
A. I'm not sure because the page numbers 10:09
don't match up in content. 10:09
Q. Did you write two versions of the 10:09
report? 10:09

A. No. 10:09
Q. Are you sure? 10:09
A. Yeah. 10:09
Q. Well, does Exhibit 94 match the one you have with you? 10:09
A. No, the page numbers are off, which may be a matter of printing possibly. 10:09
Q. Okay. Do 92 and 94 appear to be your report, even though the page numbers may be off in some way? 10:09
A. They appear to be my report. 10:10
Q. Okay. So in the process, you reviewed material, you spoke with the lawyers who retained you and then ultimately you drafted a report; correct? 10:10
A. Yes. 10:10
Q. And were you aware that in this process of drafting the report, what you were doing was putting lawyers like me who represent the pharmaceutical manufacturer on notice of what your opinions were in this case? 10:10
A. Can you say that again, please? 10:10
Q. As you went through this process, did you realize that the purpose of the report was not only to organize your thoughts but it was to put 10:10

people like me on notice of what your opinions were? 10:10

A. On notice I'm assuming is reporting the information that I saw and the conclusions I came to, yes. 10:10

Q. Yeah, put me on notice so that when I came to question you, I would have some idea as a starting point what your thoughts were; right? 10:11

A. I'm actually having difficulty here. On notice means different things to me than it may mean to you. 10:11

Q. Well, in some way you were communicating to readers -- including people like me -- what your opinions were; right? 10:11

A. Yes. 10:11

Q. And you tried to do the best you could to make your report thorough so that you would remember in an organized fashion what your opinions were; correct? 10:11

A. Correct. 10:11

Q. And these lawyers like Fred Thompson, and Meghan and Mike would know what your opinions were; right? 10:11

A. Correct. 10:11

Q. And the court presumably, if it read 10:11

your report, would know what your opinions are; is that right? 10:11

A. Correct, yes. 10:11

Q. Now, let's go to page 6. And what are you -- 10:11

A. Which version would you like me to use? 10:11

Q. Well, pick 92 or 94. Let's see if they're the same. 10:12

A. Okay. I'll look at 92. 10:12

Q. Sure. Page 6. 10:12

A. Page 6? 10:12

Q. Lower right hand corner. Look at the top. Is paragraph four the first thing on the page? 10:12

A. Review of Amide/Actavis Status of Compliance with cGMPs: My approach? 10:12

Q. Yes. 10:12

A. Yes. 10:12

Q. All right. By the way, is that the same in 94? 10:12

A. Let's take a look. It is. 10:12

Q. And the same as the version you brought with you? 10:12

A. No. 10:12

Q. Can I see the one you brought with you? 10:12

A. Yeah. It appears to be a formatting page thing. 10:12 10:13

Q. Okay. So it says here: "In order to accurately evaluate the status of Amide/Actavis's status of compliance with the CGMPs, I took the following approach." 10:13 10:13 10:13 10:13 10:13

Did I read that correctly? 10:13

A. You did. 10:13

Q. Now did the lawyers who retained you in this litigation tell you that your charge or your job in this case was to evaluate the status of my client's compliance with the GMPs? 10:13 10:13 10:13 10:13

A. Yes. 10:14

Q. And they did not tell you that your charge or your task in this case was to help them determine if out of specification Digitek actually reached the hands of consumers; correct? 10:14 10:14 10:14

A. My guidance from them was fairly general, included evaluate, in your opinion, the status of compliance with GMPs and how that may have affected a product that was potentially dangerous getting to market, Digitek being the one. 10:14 10:14 10:14 10:14 10:14

Q. Potentially dangerous? 10:14

A. Uh-huh. 10:14

Q. Right? 10:15
A. Uh-huh. 10:15
Q. You have to answer out loud. 10:15
A. Yes, I'm sorry, yes. 10:15
Q. Phil doesn't understand uh-huh, huh-uh, and shakes and nods; okay? 10:15
A. Yes, sir. 10:15
Q. So in bullet point number one, you assumed that Amide and Actavis was a new consulting client needing assistance with determining their level of compliance with the GMPs. Is that what it says there? 10:15
A. It does. 10:15
Q. And you performed a paper audit of the facility to determine past and current status of compliance; right? 10:15
A. That is correct. 10:15
Q. And then you list what your audit included; is that right? 10:15
A. That's correct. 10:15
Q. Now, how long have you been in the consulting business in the pharmaceutical industry? 10:15
A. About 12, almost 13 years. 10:15
Q. In those 12 to 13 years, how many times 10:15

have you actually been engaged by a pharmaceutical company to do a project? 10:15 10:16

A. A project? Any type of project? 10:16

Q. Any type of project. 10:16

A. How many times? 10:16

Q. Yeah. 10:16

A. It's numerous. I'd have to really sit down and think about it. 10:16 10:16

Q. How many times have you been asked by a consulting client in those 12 to 13 years to assess their status of compliance with GMPs? 10:16 10:16 10:16

A. At least five. 10:16

Q. In general, in the five times that you were retained by a pharmaceutical client to assess their GMP status, how many times in those five did you look at batch records? 10:16 10:16 10:16 10:17

A. It's tough to say. Numerous. 10:17

Q. Okay. And when you did, did you look at a lot of batch records? 10:17 10:17

A. Depends on how you're going to define "a lot." 10:17 10:17

Q. Did you look at more than one batch record? 10:17 10:17

A. Yes. 10:17

Q. Did you look at more than two? 10:17

A. Yes. 10:17
Q. Did you look at annual reports or annual 10:17
data reviews in these five times when you were 10:17
asked by pharmaceutical companies to assess their 10:17
compliance? 10:17
A. Yes. 10:17
Q. Did you look at FDA 484 testing if it 10:17
was available? 10:18
A. No. 10:18
THE VIDEOGRAPHER: We have five minutes 10:18
left on the tape. 10:18
BY MR. MORIARTY: 10:18
Q. Do you know what US or FDA 484 testing 10:18
is? 10:18
A. Generally. 10:18
Q. Okay. If the pharmaceutical clients 10:18
that you hired had hired other companies to help 10:18
them remediate 483s and warning letters, did you 10:18
look at those remediation documents? 10:18
A. Yes. 10:18
Q. Did you look at any sort of independent 10:18
testing of the product if it was available to you? 10:18
A. Yes. 10:18
Q. And just to wrap up this segment before 10:18
the tape expires, I assume that you, when you 10:18

looked at things like batch records and annual reports and annual data reviews, you would have been looking at finished product test results for various products; is that true? 10:18 10:18 10:18 10:18 10:19

A. Yes, and active pharmaceutical ingredients as well. 10:19 10:19

MR. MORIARTY: Let's take our tape break. 10:19 10:19

THE VIDEOGRAPHER: The time is a.m. We're going off the record briefly. 10:19 10:19 10:19

(Short break) 10:22

THE VIDEOGRAPHER: The time is now 10:23 a.m. We are back on record. This is the beginning of tape two. 10:22 10:22 10:22

BY MR. MORIARTY: 10:22

Q. So getting back to how you did this paper audit, another thing that I forgot to ask you about is when you have checked GMP compliance for some of your pharmaceutical clients, do you look at process validation studies? 10:22 10:22 10:22 10:23 10:23

A. I have, yes. 10:23

Q. All right. So in this litigation, how many process validation studies for Digitek did you look at? 10:23 10:23 10:23

A. None were made available to me that I recall. 10:23

Q. Did the Plaintiffs' lawyers make available to you an online repository of documents? 10:23

A. Yes. 10:23

Q. Did you look through there to see what was in there? 10:23

A. Yes. 10:23

Q. And -- 10:23

A. In detail. 10:23

Q. And process validation studies were not there? 10:23

A. At the time I reviewed it, not to my knowledge. 10:23

Q. All right. Now this is Exhibit 1. It's the Amide process validation report for Digitek, .125, at the batch size of 1,600,000 tablets. 10:24

Have you ever seen that before? 10:24

A. May I check my documents? It may have been associated with an investigation. 10:24

Q. Do you have a list so that we don't have to watch you thumb through the boxes? I mean you told me a minute ago you don't recall seeing them. I'm just trying to verify whether you've 10:24

seen this or not. 10:24

A. It could have been part of the ANDA that 10:24
I looked at and I don't recall. It might have 10:24
been part of the investigation. So it would have 10:24
been part of a document associated with this. As 10:24
far as a specific, stand-alone process validation, 10:25
I don't believe I ever saw one. 10:25

Q. Here is Exhibit 1(a), which is the 10:25
validation study for Digitek when they ramped the 10:25
.125 dose strength up to 4.8 million tablet batch 10:25
sizes. 10:25

Do you recall whether you've seen that 10:25
before? 10:25

A. I don't recall seeing this document. 10:25

Q. I'm showing you Exhibit 1(b). I believe 10:25
this is the process validation when they were 10:25
still at the batch size of 1.6 million, but at a 10:25
different press speed. 10:25

Have you ever seen that? 10:26

A. Let me check my documents, please. 10:26

Q. Go ahead. Look for every process 10:26
validation that you had because I have two more. 10:26
Look at the index or something. Are you on or 10:26
off? 10:26

THE VIDEOGRAPHER: On. Would you like me 10:26

to go off? 10:26

MR. MORIARTY: Sure. 10:27

THE VIDEOGRAPHER: The time is 10:27

a.m. We're going off the record 10:27

briefly. 10:27

(Short break) 10:30

THE VIDEOGRAPHER: The time is 10:30

a.m. We are back on the record. 10:30

BY MR. MORIARTY: 10:30

Q. So, so far, we've talked about 1, 1(a) 10:30

and 1(b). The question is are those in your 10:30

documents that you reviewed to formulate opinions 10:30

in this case? 10:30

A. Just so you know, this is a list of 10:30

every document I reviewed online. I just want to 10:32

make sure that I'm not misspeaking, so... 10:32

Q. Did you print everything you reviewed 10:32

online? 10:32

A. No, there's just too much. It does not 10:32

appear that I had access nor reviewed process 10:33

validation. 10:33

Q. Okay. So Exhibit 2, just for 10:33

completeness, this is the process validation for 10:33

the 4.2 million tablet batch sizes for .25 10:33

Digoxin. You haven't seen this document? 10:34

A. No. 10:34
Q. And Exhibit 3, did you know that 10:34
Digitek, like other Digoxin products, used to be 10:34
made in .5 milligrams? 10:34
A. I don't recall that fact. 10:34
Q. No? This is Exhibit 3. 10:34
A. Uh-huh. 10:34
Q. This is the process validation for the 10:34
.5 milligram Digitek. Have you ever seen that 10:34
document? 10:34
A. No. 10:34
Q. May I see that compendium of documents 10:34
you reviewed online but you did not print or put 10:34
in your boxes? 10:34
A. Sure. 10:34
Q. I'm going to put an exhibit sticker on 10:34
this. 10:34
A. Sure. 10:34
Q. These go together, these two? 10:34
A. Yes. 10:34
Q. Okay. 10:34
A. One's for Mylan documents and others 10:34
were a Plaintiffs' exhibit, if I'm not mistaken. 10:34
Q. Okay. So. I am going -- 10:35
A. They were organized differently on the 10:35

website. 10:35

Q. I'm going to put Exhibit 107 on the list you made of the Mylan documents and 108 on the Plaintiffs' exhibits; okay? 10:35

(Whereupon, Exhibits 107 and 108 were marked for identification) 10:35

A. Okay. 10:35

Q. I partially obscured your e-mail address for this one; okay. 10:35

Tell us all in general what process validation is briefly. 10:35

A. Briefly, process validation is just the process of following a protocol, delineating those critical components in the manufacturing process that need to be varied and see the observing effect on the product you have. 10:35

Q. Once a pharmaceutical company has validated a process in manufacturing a pharmaceutical -- 10:36

A. Uh-huh. 10:36

Q. -- does that in essence mean that they have shown that they can make the drug within its specifications consistently? 10:36

A. That is the purpose of process validation in general. However, I will tell you 10:36

this: I am not a process validation expert. I support process validation from a laboratory, cross-functional standpoint, including reviewing the protocols and looking at the samples that are to be tested and how they are to be tested. 10:36

Q. Okay. So you have been involved in process validation from the what I would call QC or lab perspective; right? 10:36

A. No, analytical R&D. 10:36

Q. Okay. 10:36

A. Which is different than a QC. 10:36

Q. Not even finished product testing? 10:36

A. No, that's not true. I've done both. 10:36

Q. Okay. But the fact is that when you have a process validation for the manufacturer of a pharmaceutical, it includes the equipment you're going to use to blend it, press it, package it, and all the steps you're going to take to test it to assure as best you can that you consistently produce the product within its ANDA or NDA or USP specs; correct? 10:37

A. In general I'd say that's a fair assessment. 10:37

Q. And when the FDA approved the ANDA for Digitek, at least at some point the FDA was 10:37

satisfied that the processes to make that drug had been validated; correct? 10:37

A. By review of the application, what was in the application and what was associated with the process validation, yes, at that time. 10:38

Q. Okay. Now have you been in the pharmaceutical business long enough to know what the batch certification program was? 10:38

A. After reviewing the documents related to this case, yes. 10:38

Q. All right. And batch certification was when you actually had to submit samples of product to the FDA from a batch before you could ship it to market; correct? 10:38

A. All I know is what I'm familiar with, with this case, that Digitek was part of that. As far as other drugs, I couldn't say. 10:38

Q. All right. So, for example, have you ever seen Exhibit 4, which was a letter from FDA to what later became my client verified or certifying that these batches could be distributed? 10:38

Have you ever seen that letter? 10:39

A. Possibly. 10:39

Q. Have you ever seen Exhibit 5? Please 10:39

take a look at Exhibit 5. 10:39

A. Uh-huh. 10:39

Q. I will tell you that it's a letter from July 1995 from the FDA to Amide exempting it from the batch certification process. 10:39

Have you ever seen that? 10:39

A. I don't recall. 10:39

Q. At least -- 10:40

A. It's possible it could be part of the ANDA package and I may have seen it, but I'm not sure. 10:40

Q. At least as of that time -- 10:40

A. Uh-huh. 10:40

Q. -- FDA was satisfied that Actavis was making this product within its specifications consistently so that it didn't need the advance approval to ship product to market. Is that essentially what that says? 10:40

A. Let me take a look at this. As I understand the batch certification process back in 1995, from what I have reviewed from these case documents, I'd say that statement is accurate. 10:40

Q. All right. Now have you heard the phrase in the pharmaceutical business a process that is in control? 10:40

A. Yes. 10:40
Q. So part of process validation is to 10:40
assure that your process is in control; correct? 10:41
A. Correct. 10:41
Q. Now, let's get back to your report and 10:41
whether you look at -- 10:41
A. Whatever copy, yeah. 10:41
Q. And just so you know, I think one 10:41
version was produced in the Philadelphia 10:41
litigation and the other was produced in the MDL. 10:41
I think that's what the difference is. 10:41
A. Okay. 10:41
Q. So you'll notice that the one on your 10:41
right, 94 -- 10:41
A. Yes. 10:41
Q. -- has a Philadelphia caption on it; 10:41
okay? See that up top? 10:41
A. Yes. 10:41
Q. So look at 92, which was your MDL 10:41
report. Now in the first paragraph, where you say 10:41
purpose. 10:41
A. Uh-huh. 10:41
Q. In the last sentence you talk about a 10:41
high likelihood that adulterated drug product made 10:41
it to the marketplace. 10:42

Do you see that? 10:42
A. Yes. 10:42
Q. And then if you go all the way back to your conclusion at page 21, you talk about adulterated product making it to the marketplace. 10:42
Do you see that? 10:42
A. Yes, I do. 10:42
Q. Now, I reviewed your report pretty carefully. 10:42
A. Uh-huh. 10:42
Q. Nowhere do I see you make any statement in this 21 page report that Digitek which was actually out of its specifications made it to the hands of consumers. 10:42
Am I correct about that? 10:42
A. In this report? 10:42
Q. Yes, sir. 10:42
A. I don't know if I agree with that. 10:42
Q. Let me ask that a different way. 10:43
A. Uh-huh. 10:43
Q. In the opinions section of your report -- 10:43
A. Uh-huh. 10:43
Q. -- anywhere do you say that out of specification Digitek made it to the hands of 10:43

consumers or to the marketplace? 10:43
A. Those specific words, out of 10:43
specification? 10:43
Q. Yes, sir. 10:43
A. I don't believe I used the term "out of 10:44
specification." However, if you look at 22, we 10:45
have an instance it goes back to my references 10:45
that there was a pharmacist in Bellingham, 10:45
Washington, who found double-thick tablets which 10:45
would be out of specification. 10:45
Q. Okay. I'm asking in your opinions 10:45
section in your report, that would be a fact upon 10:45
which you would rely. I'm asking if in any 10:45
opinion section? 10:45
A. Used the word specification? 10:45
Q. Yeah. No, out of specification. 10:45
A. Not that I recall. 10:45
Q. Is there anywhere in the opinions 10:45
section in your report where you render an opinion 10:45
that dangerous Digitek made it to the marketplace 10:45
or into the hands of consumers? 10:45
A. I did not use the word dangerous; 10:45
however, you know it's -- 10:45
Q. Is there any place? 10:45
MR. KERENSKY: Wait. He just said 10:45

"however." 10:45
MR. MORIARTY: I don't. I want answers 10:45
to my questions. 10:45
MR. KERENSKY: No, he gets to say 10:45
"however", if he wants to say "however." 10:46
MR. MORIARTY: Go ahead with your 10:46
however. 10:46
THE WITNESS: However, you look through 10:46
the literature that was available to me, it's 10:46
obvious that Digitek which was out of 10:46
specification -- thick, thin, whatever -- has 10:46
showed up several times in the marketplace. 10:46
BY MR. MORIARTY: 10:46
Q. We'll get to that. 10:46
A. Okay. 10:46
Q. Is there anywhere in your report where 10:46
you render an opinion that defective Digitek made 10:46
it to the marketplace? 10:46
A. I don't believe I used the word 10:46
"defective." 10:46
Q. Your conclusion in the both the 10:46
beginning and end is that it was adulterated; 10:46
correct? 10:46
A. Digitek that was not manufactured to its 10:46
specifications made it to the market; therefore, 10:46

by definition, it would be adulterated. 10:46

Q. Can you identify a single Plaintiff in 10:46

this litigation who received out-of-specification 10:46

Digitek? 10:47

A. An individual per se? 10:47

Q. Yeah. 10:47

A. I'm not familiar with the individuals 10:47

who found the cases. 10:47

Q. Now, you know what a -- in general what 10:47

a double-thick tablet is, do you not? 10:47

A. As described in the documents that I 10:47

reviewed, I'd say yes. I've personally never seen 10:47

any double-thick tablet. 10:47

Q. Not even in this litigation, nobody has 10:47

ever shown you one; right? 10:47

A. From what I understand, nobody retained 10:47

any of the double-thick tablets. 10:47

Q. Do you have some understanding that 10:47

somebody actually had one and threw it away? 10:47

A. I wouldn't say that I know they threw it 10:47

away. I know they had them. 10:47

Q. Oh, tell me who had one. 10:47

A. Well, first the pharmacist had one. 10:47

Q. In 2003 or 4? 10:48

A. I will take a look and see what date 10:48

that was. 10:48

Q. Trust me. It was 2003 or 2004 if you're talking about the Bellingham, Washington incident. 10:48

A. All right. 10:48

Q. Okay. So was 2003 Digitek recalled? 10:48

A. I don't recall. 10:48

Q. When was the first batch of recalled Digitek manufactured? 10:48

A. I have to look. 10:48

Q. Do you remember what the FDA said about the 2004 incident? 10:48

A. No. 10:48

Q. Do you know what an establishment inspection report is? 10:48

A. I do. 10:48

Q. Let me make sure I didn't write on this. This is the EIR from the fall of 2004. 10:48

A. Uh-huh. 10:49

Q. First of all, you know that that double-thick tablet incident was investigated by Amide; correct? 10:49

A. Investigated as part of a manufacturing investigation? 10:49

Q. Yes. 10:49

A. Yes. 10:49

Q. And you know that it was reported to the FDA in a field alert; correct? 10:49

A. I've never seen a field alert. 10:49

Q. They didn't make that available to you? 10:49

A. Not that I recall. It may have been on the list, but I do not specifically require seeing a field alert. 10:49

MR. FITZPATRICK: And could you pass Exhibit 5? 10:50

MR. MORIARTY: Yeah, but I need my copy for a second, if you don't mind. 10:50

BY MR. MORIARTY: 10:50

Q. Turn to page 6 of the 2004 EIR. 10:50

A. Exhibit 20? 10:50

Q. Yes, sir. And first of all, I don't remember. Have you seen this EIR as part of your review? 10:50

A. No, this is for a preapproval inspection for another product. 10:50

Q. Well, look at page 6. You see the bold, centered, in all cap, field alert reporting? 10:50

A. I do. 10:51

Q. All right. It describes this report from a pharmacist of a quote "thick tablet." 10:51

Do you see that? 10:51
A. I do. 10:51
Q. From lot 3611(a), with an expiration in December of '04. 10:51
Do you see that? 10:51
A. I do. 10:51
Q. Now, certainly -- withdraw that. 10:51
New Jersey District Compliance Branch was notified by the site and the investigation was completed at the time of inspection; correct? 10:51
A. That's what it says. 10:51
Q. In other words, the company told FDA about this incident; right? 10:51
A. Uh-huh. 10:51
Q. That's a yes? 10:51
A. At the time of the inspection, yes. 10:51
Q. All right. And the field alert report noted quote, "The most probable cause of the thick tablet was a set up problem"; correct? Is that what it says? 10:51
A. It says manufacturing set up problem. Set up, yes. 10:52
Q. And then it talks about procedural enhancements and training, does it not? 10:52
A. Yes. 10:52

Q. And then it says, "No additional complaints or reports of thick tablets have been received for this high volume product. The event was considered an isolated incident and corrective actions were put in place to prevent its reoccurrence. Corrective actions were verified during the inspection." 10:52

Did I read that correctly? 10:52

A. Corrective actions, procedural enhancements, review of complaint files were verified during inspection. 10:52

Q. Correct? 10:52

A. Yes, that's what it says. 10:52

Q. Do you have some reason to disagree with the FDA that this event was an isolated incident? 10:52

A. Yes, I do. 10:52

Q. Okay. Show me any evidence that you have that any extra thick tablet made it into the hands of a pharmacist or consumer after 2004. 10:52

MR. FITZPATRICK: Let me interpose an objection as to form. 10:53

BY MR. MORIARTY: 10:53

Q. What are you looking for? 10:53

A. I'm looking for an e-mail chain that shows a pharmacist somewhere in Massachusetts 10:53

found double-thick tablets in a card. 10:53

Q. Excellent. Here it is. Okay. I'm 10:53

showing you Exhibit 59. Is that the document that 10:54

you are looking at from your own file? 10:54

A. No, it's not. 10:55

Q. Yeah, it's not because my staff didn't 10:55

copy the second page. Let me see that, please. 10:55

A. Sure. The yellow tab is the specific 10:55

reference to it. 10:55

Q. Okay. That is supposed to be Exhibit 10:55

59. 10:55

A. Okay. 10:55

Q. My staff did not copy the part at the 10:55

back; okay? 10:55

A. Okay. 10:55

Q. So let me ask you some questions about 10:55

that. 10:55

It's in an e-mail; correct? 10:55

A. It is. 10:55

Q. Have you seen any evidence that that 10:55

tablet or card of tablets was returned to Actavis 10:55

or Mylan for analysis? 10:56

A. I have not seen any documentation that 10:56

shows that any chemical testing has been done on 10:56

any of the thick, thin, or whatever tablets. 10:56

Q. I didn't ask about chemical testing. 10:56
All I did was ask if you've seen any documents to 10:56
indicate that that tablet or card of tablets was 10:56
returned to Actavis or Mylan. 10:56
A. This is the only reference that I've 10:56
seen with respect to these. 10:56
Q. And it contains no statement that the 10:56
tablet or tablets were returned to Actavis or 10:57
Mylan; correct? 10:57
A. This e-mail does not say that it was 10:57
returned. 10:57
Q. Was it in a blister pack? 10:57
A. It says the card had four tablets. 10:57
Q. Do you take that to mean blister pack? 10:58
A. I'm not sure. I'm not sure what it 10:58
means. 10:58
Q. Was it removed from the card or blister 10:58
pack? 10:58
A. It says here just that the remaining 10:58
tablets are in a blister pack -- not a blister 10:58
pack but a card. That's it. That's all that it 10:58
says. 10:58
Q. Do you know anything about the 10:58
manufacturer specifications of the card or blister 10:58
pack in which those tablets were? 10:58

A. No, I don't know anything about those. 10:58
Q. So you don't know whether a blister pack would even accommodate an extra thick tablet, do you? 10:58
A. I'd have to go look at the documentation because some of the documents I reviewed with respect to UDL talks about that issue. 10:59
Q. And if this blister pack or card had been made by UDL, a double-thick tablet couldn't fit in it, could it? 10:59
A. I couldn't say. 10:59
Q. Do you remember what the specs were? 10:59
A. I don't remember the specs. 10:59
Q. Would a wise and prudent manufacturer use so much raw materials of plastic and tinfoil to accommodate more space than they needed in the blister pack? 10:59
A. Could you say that again? 10:59
Q. Would a prudent manufacturer use more plastic and tinfoil than needed to package the tablets in a blister pack? 10:59
A. I don't think you can draw the conclusion that a double tablet would not fit in a blister pack. You just don't have enough information to do that. 10:59

Q. You don't. 10:59

A. No. I don't think anybody does from the 10:59

literature I've read. 11:00

Q. Okay. Did anybody in that e-mail remove 11:00

a tablet and measure it with a micrometer? 11:00

A. Not according to this e-mail. And 11:00

that's a really interesting point out of all of 11:00

this that's very striking when you look at all the 11:00

data. 11:00

Q. You have to answer my question. 11:00

MR. KERENSKY: He just said he did. 11:00

MR. MORIARTY: I don't want a speech, 11:00

Mike. I want to know whether anybody 11:00

indicates that they removed it and measured it 11:00

with a micrometer, yes or no? 11:00

THE WITNESS: In this e-mail, no. 11:00

MR. KERENSKY: Wait a minute. Wait a 11:00

minute. 11:00

MR. MORIARTY: I'm going to let him make 11:00

his speech in minute; okay? 11:00

MR. KERENSKY: Let him finish his answer. 11:00

MR. MORIARTY: I want to ask my 11:00

questions. 11:00

MR. KERENSKY: Let him finish his 11:00

answer. Right now. 11:00

MR. MORIARTY: He did. He said correct. 11:00
MR. KERENSKY: He did not. You 11:00
interrupted him right in the middle? 11:00
Q. Now if you -- 11:00
MR. KERENSKY: Stop. The deposition is 11:00
stopped. 11:00
MR. MORIARTY: You think you have the 11:00
authority to do that under PTL 22? 11:00
MR. KERENSKY: I think I do. I'll take 11:00
the chance. Are you going to let him finish 11:00
his answer? 11:00
BY MR. MORIARTY: 11:00
Q. Go ahead and finish your speech. 11:00
A. Speech? 11:00
Q. Yeah, go ahead. 11:00
A. I -- to tell you the truth -- because of 11:00
that exchange, I don't know where the question 11:00
was. 11:01
MR. KERENSKY: Okay. Let's go back up 11:01
and pick up where he interrupted you and then 11:01
you can finish your thought. You have the 11:01
right to do that. 11:01
(Whereupon, the testimony was read 11:01
back by the court reporter, as recorded above) 11:01
MR. KERENSKY: Finish your thought and 11:01

then move on. 11:01

THE WITNESS: Yeah, it's been 11:01

demonstrated that a significant number -- when 11:01

you look at FDA findings and reports or 11:01

whatever -- of double-thick tablets that were 11:01

produced, nobody ever performed any testing on 11:01

those, according to the record that I can 11:01

find. Which is really unusual because we 11:01

don't know whether it's out of spec or in 11:01

spec, all the points that you are going to, 11:01

you just don't know because nobody apparently 11:02

did it. Or if they did it, they didn't report 11:02

it. 11:02

BY MR. MORIARTY: 11:02

Q. Are you done? 11:02

A. Yes, sir. 11:02

Q. So according to this e-mail, whatever 11:02

tablet or tablets those were -- first of all, it 11:02

only refers to one tablet doesn't it, in the 11:02

card? It doesn't say all four were double; right? 11:02

A. It says please be advised that Lynne 11:02

Farrell of CSC reports finding a card of Digoxin 11:02

with one double thick tablet at GL-Gloucester. 11:02

Q. What a CSC? 11:02

A. I don't know. 11:02

Q. So you don't know anything about the reliability of this person who supposedly found this; correct? 11:02

A. It's an e-mail. It would be difficult to do that. 11:02

Q. All right. And certainly this was not in the hands or mouth of a consumer; correct? 11:02

A. This particular one right here? 11:02

Q. Right. 11:02

A. From the e-mail, that's the conclusion you could probably draw. 11:02

Q. If you were using the scientific method to figure out -- you're called in as a consultant to find out if double-thick tablets have actually made it to the hands of consumers and you're using the scientific method with data, this e-mail is not a particularly reliable report, is it? 11:02 11:03 11:03 11:03

MR. FITZPATRICK: Object to the form. 11:03

THE WITNESS: I wouldn't consider this a report. It's a statement in an e-mail. 11:03

BY MR. MORIARTY: 11:03

Q. So it's not reliable data for you as a scientist to conclude that that was in fact a double-thick tablet; is that correct? 11:03

A. I don't think that's correct. It's 11:03

something that starts a formal investigation. It's a piece of data. 11:03

Q. With no measurement and no removal from its packaging; correct? 11:03

A. Correct. But observation is one of the critical components to scientific experiment. And observations such as this are critical when you're conducting investigations. 11:04

Q. Have you ever tried to observe the thickness down to the millimeter of a tablet in a blister pack? 11:04

A. In a blister pack? 11:04

Q. Yeah. 11:04

A. Down to the millimeter? 11:04

Q. Yes, sir. That's how thin these tablets are, isn't it? 11:04

A. I forget what the spec is for thickness. Me, personally, looking a blister pack -- 11:04

Q. Yes. 11:04

A. -- and trying to estimate what the thickness would be, no, I had no -- would have no desire or need to do that. You wouldn't estimate if you're trying to come up with a spec. You'd measure it. 11:04

Q. So we started this line of questions with you know what a double-thick tablet is or an oversized tablet; correct? 11:04

A. As they're referring to it in this deposition, yes. 11:04

Q. In any context in the pharmaceutical industry if somebody said to you we have oversized tablets or double-thick tablets, you know what that is; right? 11:05

A. This is the first time that I've heard reference in the industry to a double-thick tablet. It's that unique a situation. 11:05

Q. Okay. Do you know how many recalls there have been in the last 36 months for extra thick tablets in the pharmaceutical industry? 11:05

A. I do not. 11:05

Q. And you know what a normal tablet with too much active pharmaceutical ingredient is, don't you? 11:05

A. I don't know if I understand the question. You can't just look at a tablet and know how much ingredient is in it. 11:05

Q. I didn't imply or ask you if you could. But a normal-sized tablet could have too much active pharmaceutical ingredient; correct? 11:05

A. Yes. 11:05
Q. You could assay or content uniformity 11:05
test that tablet to determine that; correct? 11:05
A. Yes. 11:05
Q. Do you know enough about the 11:06
manufacturing process to say whether the root 11:06
cause of an extra thick is typically different 11:06
than the root cause of a normal size with too much 11:06
active pharmaceutical ingredient? 11:06
A. Say that again. 11:06
(Whereupon, the testimony was read back 11:06
by the court reporter, as recorded above) 11:06
THE WITNESS: Based on the information 11:06
and the data that I have here, Actavis 11:06
specifically indicated that there were 11:06
problems in the manufacturing of this product 11:06
very early on. It was very difficult. In 11:06
19-- whatever, 2000. And it took them a lot 11:06
to do it. And as they moved forward and they 11:07
had problems, they had problems with blend 11:07
uniformity and then obviously with 11:07
manufacturing the tablet and, therefore, it is 11:07
possible -- based on the information I looked 11:07
at -- that you could have both of those 11:07
problems because of difficulties with blend 11:07

uniformity and with tableting. It's possible. 11:07
MR. MORIARTY: Motion to strike. It was 11:07
completely non-responsive to my question. 11:07
MR. KERENSKY: He has to do that for the 11:07
judge. 11:07
THE WITNESS: I understand. 11:07
MR. KERENSKY: That's fine. 11:07
BY MR. MORIARTY: 11:07
Q. I'm talking about manufacturing tablets 11:07
and whether you have any knowledge of whether 11:07
those two distinct problems in manufacturing have 11:07
different root causes. 11:07
A. In general? 11:07
Q. Yes. 11:07
A. Say that again, please. 11:08
Q. Okay. 11:08
A. Because it's a very broad statement. 11:08
Q. Let's get back to basics. 11:08
A. Okay. 11:08
Q. If somebody says you have extra thick or 11:08
double-thick tablets, that's a reference to size; 11:08
correct? 11:08
A. I would assume so, yes. 11:08
Q. All right. And that size could be 11:08
caused by too much active pharmaceutical 11:08

ingredient, too much excipient, inadequate compression making a fluffy tablet, double compression, could be caused by any number of things; correct? 11:08

A. That's -- there are many things it could be, yes. 11:08

Q. All right. So a normal-sized tablet with too much active pharmaceutical ingredient is a different problem in the pharmaceutical manufacturing process, isn't it? 11:08

A. I don't think you can say that exclusively. I think that, you know, it's a manufacturing train, it's a process. And if you don't have control of your process, it's possible to have those two events as a failure in the process. 11:09

Q. I'm not asking whether you can only have one or the other. I'm asking whether they're different. And if a tablet is normal-sized, by definition it's not extra-thick or double-thick; correct? 11:09

A. Yes. 11:09

Q. So a normal-sized tablet with too much ABI, the problem is the amount of active pharmaceutical ingredient; correct? 11:09

A. I'm not trying to be difficult. I'm just trying to understand the question here. I apologize. 11:09

Q. If I said to you -- 11:09

A. Uh-huh. 11:09

Q. -- Mr. Bliesner, I want you to come in and consult with my pharmaceutical manufacturing company. 11:09

A. Uh-huh. 11:10

Q. Our tablets are double-thick. 11:10

A. Uh-huh. 11:10

Q. And I tell you nothing more. 11:10

A. Uh-huh. 11:10

Q. The problem is a size problem to start with; correct? 11:10

A. Uh-huh. 11:10

Q. Is that a yes? 11:10

A. Double-thick, yes. 11:10

Q. All right. At some point you'd get to the issue of what the active pharmaceutical content of those tablets is if you were doing an investigation; correct? 11:10

A. Yes, it would be one of the first things you'd do. 11:10

Q. But if I told you that my problem was 11:10

normal-sized tablets with too much API, the investigation process would be different, correct, because the problem is different. 11:10

A. Actually, no. 11:10

Q. All right. Well, the focus would be on why is there too much API; right? 11:10

A. I don't think you'd look at those things mutually exclusively. 11:10

Q. Do you think the FDA knows the difference between extra-thick tablets and tablets of normal size but too much Digoxin? 11:10

A. I'm sure they do. 11:11

Q. Have you seen the FDA approved press release for this recall? 11:11

A. I'm not sure. 11:11

Q. There you go. Exhibit 36. Have you seen this? 11:11

A. Yes, I have. 11:12

Q. Okay. It says: 11:12

"The voluntary all-out recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released." 11:12

A. It does say that. 11:12

Q. And in this sentence, the words 11:12

"possibility" and "may" are different than "probability" "likely" and "certainty"; correct? 11:12

MR. KERENSKY: Objection, vague. 11:12

BY MR. MORIARTY: 11:12

Q. Is that right? 11:12

A. Again, we're back to the definition of "probable" and "possible." 11:12

Q. Which you don't know the difference; right? 11:12

A. In the context in this industry, as having sat down and thought about it, like I said before, no. 11:12

Q. Well, at least the sentence "FDA approved" doesn't say that we know for a fact that double-thick tablets were commercially released; right? It doesn't say that. 11:12

A. It does not say that. However, I have never seen a recall notice that says absolutely. This is the way they're stated. 11:13

Q. And then it says these tablets may contain twice the approved level of active ingredient than is appropriate; correct? 11:13

A. It does say that. 11:13

Q. Have you seen any FDA document which says that this recall was for normal-sized tablets 11:13

with too much active pharmaceutical ingredient? 11:13
A. Recall document? 11:13
Q. Any document. Any -- 11:13
A. Any document? 11:13
Q. Any document from the FDA. 11:13
A. Say it again. Again -- 11:13
Q. Have you seen any -- 11:13
A. -- I'm not trying to be difficult. I 11:13
just want to make sure I answer your question 11:13
correctly. 11:13
Q. Have you seen any document from the 11:13
FDA -- whether it's a paper they promulgated, a 11:14
report, or a 483 warning letter, anything -- or 11:14
even their website -- to indicate that this recall 11:14
was for normal-sized tablets with too much 11:14
Digoxin. 11:14
A. Not that I recall. 11:14
Q. To your recollection, did the FDA ever 11:14
cite, warn, or observe that Digitek with normal 11:14
size but too much active pharmaceutical ingredient 11:14
had reached the marketplace? 11:14
A. Can I take a look real quick at my 11:15
report? 11:15
Q. Sure. 11:15
A. My notes and my report, I don't have any 11:18

record of the FDA making a statement like that. 11:18

Q. Please look at Exhibit 38. Terry, I'll give you a copy. 11:18

Do you know if you've ever seen this before, Mr. Bliesner? 11:18

A. I think I may have. 11:18

Q. All right. Exhibit 38 is a printout from the FDA's website. I believe this was posted in July of 2009, a year and a quarter after the recall. 11:18

Go to the second page, please. 11:19

A. Uh-huh. 11:19

Q. First of all, this is called Facts and Myths About Generic Drugs; right? 11:19

A. Yes. 11:19

Q. And on the second page it says, "Myth, there are quality problems with generic drug manufacturing. A recent recall of generic Digoxin -- called Digitek -- shows that generic drugs put patients at risk." 11:19

Did I read that correctly? 11:19

A. Yes. 11:19

Q. And then it says, "Fact. FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs -- 11:19

generic and brand name -- are held"; correct? 11:19
A. Correct. 11:19
Q. All right. Let's go down to the third 11:19
bullet point. 11:19
A. Yes. 11:19
Q. Well, actually, let's go to the second 11:19
bullet point. Well, I'm sorry. Withdraw that. 11:20
Look at the first three bullet points. 11:20
A. Okay. 11:20
Q. All right. What they are describing in 11:20
the first three bullet points is the incident in 11:20
November, December, January 2007 to 2008 regarding 11:20
batch 70924 with the 20 double-thick tablets; 11:20
correct? 11:20
A. I don't know if that's the specific 11:20
batch. I'd have to go back and look it up. 11:20
Q. Trust me. 11:20
A. Yeah. 11:20
Q. Okay. That's that they're talking 11:20
about; right? 11:20
A. It appears. 11:20
Q. All right. So in the third bullet point 11:20
it says: 11:20
"Although Actavis attempted to remove the 11:20
affected Digitek through visual inspection, FDA 11:20

determined that this method of removal was inadequate to assure the product quality and consistency in accordance with the current good manufacturing practice regulations"; correct? 11:20 11:20 11:21 11:21

A. Sure. 11:21

Q. So what they're referring to is an inspection issue; is that right? 11:21 11:21

A. A visual inspection. 11:21

Q. Yes. 11:21

A. Correct. 11:21

Q. Bullet point 4, second sentence: 11:21

"In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely." 11:21 11:21 11:21 11:21 11:21

First of all, did I read it correctly? 11:21

A. You read it as written. 11:21

Q. Do you have some reason to disagree with the FDA's findings in this regard? 11:21 11:21

A. Absolutely. 11:21

Q. What's the basis for your disagreement with FDA? 11:21 11:21

A. My disagreement with FDA, first of all, there's political overtones that are always 11:21 11:21

associated with these statements reporting to the press at the FDA. And if you go back and look at the FDA's record over the course of, you know, the last 20 years if you will, approximately, go back and look at the timeline, the FDA has repeatedly found this company to be in significant violation of the GMPs. To my knowledge, this is only company that's ever been under consent decree twice. 11:21 11:22 11:22 11:22 11:22 11:22 11:22 11:22 11:22

Q. Are you done with your answer? 11:22

A. For now, yes. 11:22

Q. Okay. Can you explain to us all, please, what expertise you have in the political analysis of the FDA? 11:22 11:22

Can you explain that to me, please, what expertise you have from your background, training, and experience, that you can assess the political overtones or motivations of this statement on the website? 11:23 11:23 11:23 11:23

A. In my experience, recent experience, I see serious discussions that go on between two major branches within the FDA that are often in conflict with one another. Drug shortage, for instance, and compliance. And they are very politically motivated and their purpose is that 11:23 11:23 11:23 11:23 11:23

their ends are -- end missions are different. 11:23
That's my experience of it. 11:24
Q. Is that a scientific opinion? 11:24
A. We're talking about politics. 11:24
Q. Okay. So what would be the political 11:24
motivation a year and a quarter after a recall for 11:24
them to say this about the number of defective 11:24
tablets that may have reached the market and the 11:24
level of risk to consumers? 11:24
A. Why would they say that? 11:24
Q. Yeah. What data do you have to say that 11:24
this is somehow politically motivated? What's 11:24
your -- what's your underlying data? 11:24
A. The underlying data is their 11:24
documentation in the establishment inspection 11:24
reports that shows gross violation of the GMPs 11:24
throughout the history of this company and that 11:24
they approved them after the first consent decree 11:24
as being okay and they ended up right back in the 11:24
same place. So I would be hard pressed to want to 11:24
admit in public that they may have potentially not 11:24
served their mission correctly after the first 11:25
consent decree. 11:25
Q. So if I understand what you're saying, 11:25
the FDA soft-pedaled this statement about the 11:25

Digitek recall to deflect attention from their lack of oversight for the company; is that right? 11:25

A. Politically it's a possibility. 11:25

Q. Is it a probability? 11:25

A. I don't -- I don't agree with that statement. 11:25

Q. Is it a probability? 11:25

A. I couldn't go anywhere back to possibility, probability either. 11:25

Q. Is it a certainty? 11:25

A. I don't know. We're talking politics here, we're not talking science. We shifted from science to politics. 11:25

Q. I didn't; you did. I'm asking whether you have some data to support the opinion you're now giving. 11:25

A. It's my opinion and it's a political one. And there are no direct data other than the FDA's voluminous EIR 483 inspections, warning letters. 11:25

THE VIDEOGRAPHER: The time is . We are going off the record briefly. 11:26

(Short break) 11:31

THE VIDEOGRAPHER: The time is now 11:31

11:32 a.m. We are back on the record. This 11:31

is the beginning of tape three. 11:31

BY MR. MORIARTY: 11:31

Q. Mr. Bliesner, the -- or Dr. Bliesner I'm 11:31
sorry -- the -- I haven't asked you this in any 11:32
detail. I will get to it later. 11:32

I assume that your opinions in this case about 11:32
adulterated product are based on 483s; is that 11:32
correct? 11:32

A. Partially. 11:32

Q. And warning letters? 11:32

A. Partially. 11:32

Q. And establishment inspection reports? 11:32

A. Partially. 11:32

Q. Those are all FDA documents; correct? 11:32

A. Correct. 11:32

Q. And are they based on the fact that 11:32
there have been two consent decrees? 11:32

A. What's based on two consent? 11:32

Q. Your opinions. 11:32

A. Partially. 11:32

Q. Okay. And those are, although not FDA 11:32
documents, they're negotiated with the FDA; is 11:33
that correct? 11:33

A. Consent decree? 11:33

Q. Yeah. 11:33

A. Yes. 11:33
Q. Okay. So what other documents besides 11:33
FDA documents are your opinions based on that my 11:33
client made adulterated Digitek, in general? 11:33
A. In general? 11:33
Q. Yeah. 11:33
A. E-mail communications within the 11:33
company. Responses to 483 warning letters. 11:33
Q. Anything else? 11:33
A. Investigations. 11:33
Q. Those are by the FDA; correct? 11:33
A. A. No, internal investigations. 11:33
(Interruption) 11:34
MR. MORIARTY: We can go off the record. 11:34
THE VIDEOGRAPHER: The time is now 11:34
11:33 a.m. We are going off the record. 11:34
(Short break) 11:35
THE VIDEOGRAPHER: The time is now 11:35
a.m. We are back on the record. 11:35
THE WITNESS: The Marine Corps kicked in 11:35
there for a second. 11:35
BY MR. MORIARTY: 11:35
Q. Have any of the companies that you 11:35
worked for in the pharmaceutical business or with 11:35
which you've consulted had recalls? 11:35

A. Yes. 11:35

Q. Have there been recalls in your 11:35
experience where there was no actual proof that 11:35
there was out of specification, dangerous product 11:35
in the market? 11:35

A. I'm sorry. Still a bit distracted. 11:35
Please. 11:35

Q. Okay. In your experience, have there 11:35
been recalls of pharmaceutical product to the 11:35
consumer level where there was no actual proof 11:35
that there was out of specification, dangerous 11:36
product in the hands of consumers? 11:36

A. I can't think of a specific example. 11:36

Q. In general have there been? 11:36

A. Possibly. 11:36

Q. Okay. So, for example, there could be a 11:36
recall of a drug product because of a packaging 11:36
issue. The label might be on upside down; is that 11:36
right? 11:36

A. Correct. 11:36

Q. So the mere fact that there's a recall 11:36
does not in and of itself mean that the product is 11:36
out of spec and dangerous to the consumer; right? 11:36

A. That's correct. 11:36

Q. You want to know more about that if 11:36

you're going to -- if you're going to determine whether it's actually out of spec and dangerous to consumers, you want to know more than just the fact that there was a recall; right? 11:36

A. Yes. 11:36

Q. Okay. Now, if the FDA says in effect that a product is adulterated, does that always lead to a recall? 11:36

A. No. 11:37

Q. Why not? 11:37

A. Numerous reasons it could be that way. 11:37

Q. Give me some, please. 11:37

A. Hasn't shipped is the first thing that comes to mind. 11:37

Q. Okay. 11:37

A. That would be the primary one. 11:37

Q. Any others? 11:37

A. No. But, I'm not an expert in recalls. 11:37

Q. Okay. Well, the FDA could determine that there is adulterated product and have a recall not to the consumer level also; correct? 11:37

A. As I understand, yes. 11:38

Q. In other words, the FDA in effect is making a determination that whatever product is being recalled isn't necessarily dangerous to the 11:38

consumers; right? 11:38

A. A recall can be of something that isn't necessarily an immediate danger as I understand it, not being an expert in recalls. 11:38

Q. Okay. So I'm showing you Exhibit 39. Have you ever seen that before? 11:38

A. I don't think so. 11:39

Q. All right. This is a printout from the FDA's website. 11:39

A. Uh-huh. 11:39

Q. And it's entitled "Facts About Current Good Manufacturing Practices"; correct? 11:39

A. It is titled that, yes. 11:39

Q. And the fourth bold section down, says: 11:39

"If a manufacturer is not following cGMPs, are drug product safe for use; correct"? 11:39

A. It is. 11:39

Q. The first sentence reads, "If the company is not complying with cGMP regulations, any drug it makes is considered adulterated under the law." 11:39

Did I read it correctly? 11:39

A. You did. 11:39

Q. Do you agree with it? 11:39

A. By definition, I would agree with that. 11:39

Q. The next sentence says: 11:39
"This kind of adulteration means that the 11:39
drugs was not manufactured under conditions that 11:40
complied with GMP, cGMP." 11:40
Did I read it correctly? 11:40
A. You did. 11:40
Q. Do you agree with that? 11:40
A. By definition, yes. 11:40
Q. The next sentence says: 11:40
"It does not mean that there is necessarily 11:40
something wrong with the drug." 11:40
Did I read it correctly? 11:40
A. You did. 11:40
Q. Do you agree with it? 11:40
A. Something wrong with the drug? It's a 11:40
broad statement; but as it's written, I would 11:40
agree. 11:40
Q. All right. So in other words, the fact 11:40
that a drug may be considered adulterated does not 11:40
necessarily mean that it is outside its 11:40
specifications; right? 11:40
A. Yes. 11:40
Q. Because a drug could be adulterated for 11:40
a lot of different reasons having nothing to do 11:40
with the potency of the drug; right? 11:40

A. Correct. 11:40

Q. Do you know how many batches of Digitek were involved in the recall in 2008? 11:41

A. Off the top of my head, no. 11:41

Q. How many batch records did you look at? 11:41

A. For? 11:41

Q. Digitek. 11:41

A. I looked at the batch records during the ANDA, and I don't recall the number that were in there. 11:41

Q. Is that all? 11:42

A. I'd have to check. Do you want me to take the time to do that? 11:42

Q. Well, let me ask you this: Did you look at the batch that was involved in the double-thick investigation in 2007 and 8? Did you look at the batch record, I should say. 11:42

A. I looked -- I'm pretty sure I've looked at the investigation. And how much the batch record was part of that, I'm not sure. I'm pretty sure I looked at that investigation. 11:42

Q. But you're not sure if you've ever looked at that entire batch record? 11:42

A. No. 11:42

Q. And other than -- 11:42

A. No. 11:42
Q. -- what was in the ANDA, you can't tell me that you looked at any other Digitek batch records? 11:42
A. No, I haven't. 11:43
Q. All right. Do you know how many tablets would have been involved in the Digitek recall? 11:43
A. Since I don't know how many batches there were and what the exact number without looking at it is, I couldn't tell you. 11:43
Q. All right. Do you know how many other recall batches were of the dose level of .125? 11:43
A. Again, the same answer. I don't remember the batches there were without referring -- knowing how many tablets per batch, what they would be. 11:43
Q. Do you have an opinion to a reasonable degree of probability -- in other words, more likely than not. 11:43
A. Probability more likely than not? 11:43
Q. How many of the Digitek tablets that were recalled were outside their size specifications? 11:43
A. Okay. 11:44
Q. Are you writing on an Exhibit? 11:44

A. Oh. 11:44
Q. A marked Exhibit? 11:44
A. Yes. I'm sorry. That's my notes. 11:44
MR. KERENSKY: Maybe we should put the 11:44
pen away. 11:44
THE WITNESS: Take them away from me. 11:44
Sorry. 11:44
MR. MORIARTY: Kind of like guns. The 11:44
problem is the pen, not the paper; okay. 11:44
BY MR. MORIARTY: 11:44
Q. Do you remember my question? Do you 11:44
remember my question? 11:44
A. No, I don't remember. 11:44
Q. Do you have an opinion to a reasonable 11:44
degree of probability how many of the recalled 11:44
Digitek tablets were outside their size 11:44
specifications? 11:44
A. The recalled batches in the total 11:44
number? 11:44
Q. Yeah. 11:44
A. Since I don't know how many are out 11:44
there, there's no way in the world that I could 11:44
estimate that. 11:44
Q. Do you have an opinion to a probability 11:44
of how many recalled Digitek tablets were outside 11:44

their United States pharmacopeia specifications for active pharmaceutical ingredient? 11:45

A. In my opinion, I don't think there's enough information for anybody to determine that. 11:45

Q. Now, have you ever seen a report of a Digitek tablet from a Plaintiff in this litigation that was outside its size specifications? 11:45

A. Say that again, please. 11:45

Q. Sure. In the course of your work -- 11:45

A. Yes. 11:45

Q. -- to prepare for this report -- 11:45

A. Yes. 11:45

Q. -- for today's deposition -- 11:45

A. Yes. 11:46

Q. -- have you seen either a tablet or the report of a tablet from a Plaintiff in the litigation that says that that tablet was outside its size specifications? 11:46

A. I would need to check the report again to make sure. 11:46

Q. You can, but I guarantee you there was no discussion of such thing in your report. But if you'd like to check, you go right ahead. 11:46

A. I would. 11:46

Q. While you're looking, I want you to also 11:46

look to see whether you have any report from a Plaintiff in this litigation of a Digitek tablet that was normal in size but had too much active pharmaceutical ingredient; okay? 11:46

A. Uh-huh. Sure. 11:46

Q. Are you done? 11:50

A. Yes. Plaintiff, again, is the people bringing the lawsuit? 11:50

Q. Yeah. 11:50

A. No, I don't have any reference in any report. 11:50

Q. Okay. How often do you look at the FDA's website in your work? 11:50

A. Daily. 11:50

Q. What would be a common source of reference for you? 11:50

A. The source of references has to do with recall notice, Cedar newsletter, 483 reading, that kind of thing. 11:50

Q. So you rely on the information in the FDA website for part of your day-to-day work in your consulting business? 11:51

A. I rely on it to see what the trends are with respect to compliance enforcement and to use examples for my clients of what not to do. 11:51

Q. If a company was consistently manufacturing a drug with too much active pharmaceutical ingredient in it; okay? 11:51

A. Okay. 11:51

Q. Would that likely be reflected in the inventory usage cards? 11:51

A. When you say inventory usage cards, what are you calling inventory usage cards? 11:51

Q. Do you know what inventory usage cards are? 11:52

A. I've never heard that term. 11:52

Q. In your experience do your clients and did the companies for which you worked keep documentation of their inventory of raw materials? 11:52

A. Oh, absolutely, yes. 11:52

Q. So they could calculate how often they needed to buy new material; correct? 11:52

A. That's true. 11:52

Q. And whether their usage of those raw materials was consistent with the number of batches that they were producing; right? 11:52

A. That's correct. It's part of the control of the materials. 11:52

Q. So if a company hypothetically was consistently producing a drug with too much active 11:52

pharmaceutical ingredient, would it likely be somehow reflected in the inventory documentation for the active pharmaceutical ingredient at that company? 11:52

A. Not necessarily. 11:52

Q. Why not? 11:53

A. If you have blend uniformity problems for instance, you could be making sub-potent and super-potent tablets all at the same time and that would never reflect in an actual reconciliation with your raw materials. There wouldn't be a difference. 11:53

Q. Did FDA ever cite, warn, or observe that Actavis was making Digitek with batches that had super- and sub-potent tablets in it? 11:53

A. Did they ever -- say that again, please. 11:53

Q. Cite, warn, observe. In other words, did you see a warning letter, an EIR, or a 483, some statement from FDA that Digitek had batches with super- and sub-potent Digitek in it? 11:53

A. They make reference to thick and thin tablets, but I don't recall specifically if they -- that's associated with super or sub-potent. 11:54

Q. Okay. If a company was consistently 11:54

manufacturing tablets with too much active pharmaceutical ingredients, is it likely that that would be detected at the blend uniformity stage? 11:54

A. If you've got problems with blend uniformity, it's going to be picked up on testing. 11:54

Q. Okay. Now -- and if a company was consistently manufacturing a pharmaceutical product with too much active pharmaceutical ingredient, isn't it likely that that would be detected on finished product testing? 11:54

A. Yes. 11:54

Q. Can you show me anything in a batch record or an FDA record to indicate that there was a problem with Digitek having finished product testing of out of spec Digitek with too much active pharmaceutical ingredient in it? 11:54

A. FDA or Actavis both? 11:55

Q. Let's start with FDA. 11:55

A. Okay. There's reference to difficulties on content uniformity testing. 11:55

Q. With Digitek? 11:55

A. Content uniformity in general if I'm not mistaken, yes. 11:55

Q. I want to know about Digitek. 11:55

A. Uh-huh. 11:55

Q. We're here about Digitek. These people represent people who took Digitek. 11:55

A. Uh-huh. There are documents with respect to content uniformity issues. 11:55

Q. Show me a document from the FDA or quite frankly even from Actavis to indicate that there were content uniformity problems with Digitek in 2005, 6, 7 or 8. 11:55

A. This could take a while just so you know. 11:56

Q. Well -- 11:56

A. I've looked at thousands and thousands of pages of information. And to answer a specific question accurately and precisely, it's a non-trivial thing. 11:56

Q. Okay. Take your time. I want to know what documents you have in all this material to indicate that FDA or Actavis was having an out-of-specification finished product testing with Digitek in 2005, 6, 7 or 8? 11:56

A. Content uniformity, yes, with respect to blend. 11:56

Q. Or assay. I'm talking about finished product -- 11:56

A. Finished product. 11:56

Q. -- testing? 11:57
A. No. In finished product, no. I'm 11:57
sorry. I misunderstood you because there are 11:57
issues with respect to blend uniformity; okay. 11:57
Nobody has ever tested the tablets that were 11:57
in question. Nobody that I know of. 11:57
Q. Nobody that you know of? 11:57
A. Not that I know of. 11:57
Q. Okay. 11:57
A. Which is strange in itself. 11:57
Q. Wouldn't it be required that Actavis 11:57
test every batch for assay, content uniformity, 11:57
dissolution, and then later certain batches tested 11:57
on stability? 11:57
A. Absolutely. And they would also be 11:57
expected to test those tablets that were found to 11:57
be double. 11:57
Q. I'm not asking you that. 11:57
A. Okay. 11:57
Q. So let's assume there were 152 recalled 11:57
batches, okay, that made it to market. 11:57
A. Uh-huh. 11:57
Q. Isn't it reasonable to assume that the 11:57
batch records for those 152 batches have finished 11:57
product testing data in them? 11:57